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POLICY & ACTION FROM CONSUMER REPORTS

August 12, 2014

Submitted via email: data@finance.senate.gov

United States Senate
Committee on Finance
Washington, DC 20510-6200

Re: Request for feedback on Next Steps on Health Care Transparency

Dear Senators Wyden and Grassley:

Consumers Union, the policy and advocacy division of Consumer Reports, appreciates the opportunity to provide input on next steps on health care transparency. We are pleased to see interest and activity in this very important area and urge you to press forward in improving data collection, use, and public distribution, while also protecting consumer privacy and data security. The benefits of doing so are clear: engaged consumers actively participating in their health care with improved health outcomes, research data that benefits overall population health, and a more effective and efficient American health care system.

In the first instance, we encourage you to work to make all information relating to federal health programs publicly available online. Providing the databases in easily downloadable formats, with coding translations, on websites that are easy to search and find will ensure that the wealth of health data already collected by the federal government is accessible and readily usable.

Our answers to the questions specifically laid out in the letter soliciting comments are as follows.

I. What data sources should be made more broadly available?

With more detail provided in the following sections, we strongly support making the following categories of data sources more broadly available:

1. Quality and safety of health care (measured in terms of health outcomes rather than checklists);
2. Cost of health care;

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3. Data which the public has explicit permission to see, such as all health insurance rate review filings; and
4. Data that impacts the public's understanding of the efficacy of drugs or devices, such as the result of medical trials.

II. How, in what form, and for what purposes should this data be conveyed?

A: Information must be more accessible to consumers in general

We believe that increasing transparency includes making information physically and/or technologically accessible. Further, the data must be described in a way that makes it usable, with the appropriate documentation/data dictionaries. Materials must also be comprehensive, in full, non-summarized and un-redacted form. The following examples illustrate how comprehensive, comprehendible, and accessible information could readily be developed:

- The federal government should do what it can to connect information that it holds with consumer-friendly, single points of entry. For instance, Hospital Compare[1] could have a live link for each hospital's quality information that clicks through to a page showing historic progress over time (using information previously published); Medicare sanctions based on inspections or fraud investigations; and inspection documents (Form 2567s) that find problems - these are public, but not easily accessible.
- Accessibility to communicators, such as media, researchers, analysts. As Medicare did with physician billing data, similar health information should be available on all providers as encouragement for third party analysts to find the stories to tell the public.

B: The following specific information must be more accessible to consumers

National, comprehensive electronic claims datasets: Electronic health care claims data not only need to be made publicly available, they need to be warehoused in an "all payer database" (also known as All-Payer Claims Databases or "APCDs"). Keeping data in silos by data type severely limits its usefulness. Also, there is redundancy in maintaining multiple silos (e.g. creating, assigning and maintaining provider identifiers and unique patient identifiers). Even where a given state has an APCD it cannot readily be combined with another state's APCD to query and make use of a multi-state APCD. So the result is a very insular and relatively small universe of data.

The ideal is to realize one national APCD with the following attributes:

- All lives (e.g. commercially insured, Medicaid, Medicare, uninsured lives);
- Demographic information ("de-identified" in a format that is impossible to be pieced together) for longitudinal and other performance measurements, e.g. zip code, age, gender;

[1] Available here.

- National Provider Identifier (NPI) that identifies the individual clinician, and affiliations related to the provision of care (e.g. clinic, the physician in instances where a clinician (e.g. RN) is practicing under a physician's license, medical group, health plan the service is provided under);
- All health care claims, and encounter data where integrated systems do not have claims data, (e.g. hospital, clinician, medications, DME, long term care, home health, hospice), "de-identified" in a format that is impossible to be pieced together to fully protect patient privacy;
- Noting when a death occurs by integrating death certificate data. Death is a fundamental outcome measure and knowing date of death is needed for other measures (e.g. appropriate use of / access to hospice six months prior to death); and
- The ability to utilize the national dataset for benchmarking, risk adjustment, and provider quality measurement.

Diagnostic results: the anonymized results of diagnostics (i.e. imaging, lab values) should be captured electronically and made part of public use data sets, with data available for analysis but not linked to identifiable data. To that end, all information should be "de-identified" in a format that is impossible to be pieced together to fully protect patient privacy. These results would be captured in the outpatient setting, at hospital admission and throughout the inpatient stay and other settings as well.

Complaints by the public: the public's complaints against health care providers and facilities filed with a body charged with receiving and/or such complaints. All information should be "de-identified" in a format that is impossible to be pieced together to fully protect patient privacy. The complaints registered and their outcomes should be made available in such a manner they can be readily queried to:

- Identify provider name, and where salient, facility / organization; and
- Measure quality of the provider performance.

Examples of present entities and records this would apply to include hospital complaints provided with Quality Improvement Organizations (QIOs), complaints against a physician filed with a State licensing / disciplinary board, and complaints filed with state health departments that license hospitals and other facilities and professionals.

Results of regulatory actions by entities charged with monitoring health care providers (facilities and professionals): inspection results, actions taken and resolutions regarding health care provider and entity performance by a body charged with such duties. The results, actions and resolutions should be made available in such a manner that they can be readily queried to: (1) identify provider name and, where salient, facility / organization; and (2) measure quality of the provider's performance. This recommendation would apply to:

- Warnings, sanctions and fines levied on a physician by a state licensing board;
- Declarations of immediate jeopardy of a hospital levied via state or federal inspections. A complete, nationwide dataset, updated quarterly, of the hospitals that fall under "Immediate Jeopardy" status, a status that if not

corrected would lead to a hospital losing reimbursement status from CMS, should be made available to the public;

- Hospital accreditation surveys completed by accrediting agencies, such as The Joint Commission, that allow hospitals to retain a "deemed status" to serve Medicare patients. This information is critical to understanding the level of compliance with Medicare conditions of participation and should be publicly available in exchange for hospitals being eligible to serve Medicare patients. This should include initial survey findings as well as follow-up survey findings which take place weeks later after remedial action may have been taken. Currently, the results of hospital accreditation surveys cannot be accessed by the public under Section 1865 [42 U.S.C. 1395bb] (b) of the Social Security Act which reads as follows:

  > (b) The Secretary may not disclose any accreditation survey (other than a survey with respect to a home health agency) made and released to the Secretary by the American Osteopathic Association or any other national accreditation body, of an entity accredited by such body, except that the Secretary may disclose such a survey and information related to such a survey to the extent such survey and information relate to an enforcement action taken by the Secretary.[2]

- Federal inspections of diagnostic equipment.

Ratings of transplant facilities: In the past, ratings of transplant facilities were publicly reported by UNOS on outcome measures such as mortality, but that is no longer the case. A person can request performance results for one facility. But it is unclear what the results are and the results for one facility do not allow one to compare across facilities. The U.S. Department of Health and Human Services (HHS) should create an entity to either design and deploy:

- A registry data set sufficiently robust for a measure developer to create surgeon level and facility level outcome measures, or
- Outcome measures, e.g. inpatient mortality, mortality at various increments post-discharge, readmissions at various increments post-discharge, inpatient adverse events (e.g. infections), and adverse events at various increments post-discharge.

Price information: transparency is an important part of the value equation, compared against quality of care with special consideration to patient safety. Consumers and other purchasers need to know what they are paying for before they choose and receive care. There are three main prices that stakeholders must know: (1) provider prices, (2) medical device prices, and (3) pharmaceutical prices.

Provider price transparency: following medical care, consumers may receive bills from their physician, the hospital or health center where care was received, and from auxiliary health professionals. In many cases, contracts between insurance carriers and providers contain provisions—known as gag clauses—that prevent certain cost and quality information from being made public. Some jurisdictions,

[2] Sec. 1865. [42 U.S.C. 1395bb] available here.

such as the state of California[3], have independently limited these gag clauses, freeing plans to provide such data to its enrollees and other purchasers. We believe this sort of limitation should be nationwide.

Medical device price transparency: Equally important to medical care price and quality information is readily available data on medical devices, which can carry very high-cost and medical high-risk. According to a Medicare study by the GAO, lack of price transparency may hamper hospitals' ability to be prudent purchasers of implantable medical devices.[4] Several Senators have proposed legislation banning confidentiality clauses in contracts for devices in the past[5] and Consumers Union hopes this inquiry signals another opportunity to move forward on this and related issues.

Pharmaceutical prices: there should be complete transparency in the discounts received by hospitals and clinics participating in the 340B program, which requires drug manufacturers to offer discounts to some hospitals and clinics serving low-income patients.

Health insurance rate filings: This summer, health insurers filed their 2015 health insurance rate requests. The degree the filings are available and subject to public scrutiny vary dramatically from state to state and are largely dependent on state law and leadership. HHS – which receives all rate filings from around the country – failed to make the rate data in its possession fully available to the public as well. The information HHS did make available was not readily accessible or complete; thus, it was not useful for consumers wishing to participate in the 2015 rate review filing comment period. To that end, Consumers Union joined with over-seventy co-signors in a letter to HHS[6] demanding more transparency. The federal government needs to do better in the coming year to ensure fairness of insurance rates and equality of information available to the public regardless of state residency.

Data that impacts the public's understanding of the efficacy of drugs or devices must be more accessible. Specifically, findings from clinical trials must be more transparent, not treated as proprietary information controlled by pharmaceutical and medical device companies. The FDA should make all information submitted for the approval of drugs and devices more readily available. In particular, any data derived from research that is supported by public funding (e.g. NIH, AHRQ, etc) should be made available to the

[3] California banned hospital gag clauses in 2011, with an updated bill signed by the Governor in 2014. See CA SB 1340, available here.

[4] GAO-12-126: Published: Jan 13, 2012. Publicly Released: Feb 3, 2012, available here.

[5] In 2007, Senators Grassley and Specter authored a *Transparency in Medical Device Pricing Act* (see Press release, Grassley, Specter Introduce Transparency in Medical Device Pricing Act, 23 Oct. 2007, available here.

[5]In May 2014, Senator King filed an amendment to a tax relief bill that would prohibit device companies from making hospitals sign confidentiality clauses preventing them from sharing the pricing of devices. The amendment would also have allowed the Department of Health and Human Services (HHS) to collect and make public medical device prices in an effort to help hospitals negotiate better prices for critical medical devices (see Press release, King Calls on Medical Device Industry to Increase Transparency for Price Information, 3 June 2014, available here.

[6] Letter to HHS from Consumers Union with over-seventy co-signors is available here.

public immediately. Further, we need more transparency on clinical trials that *fail to produce expected results* to bring the cost of research down by avoiding duplication of efforts. We also request that FDA release, without the requirement of a FOIA, all clinical trial data that are used as the basis for approval for medications and medical devices, even when that data is unpublished.

In addition, we request the release of bioequivalence data for generic drugs. We support the approach taken by the European Medicines Agency (EMA) on publication and access to clinical-trial data submitted to the agency.[7] The EMA will soon make available data and results from clinical trials (CTs) on which the agency bases its regulatory decisions, allowing other companies and researchers to have a more complete picture of what is known about a product's safety and efficacy. Currently much research is never published, keeping the public from benefiting from what the researchers learned.

We further request greater transparency with regard to FDA's processes during rulemaking and other regulatory actions. For each of FDA's initiatives, the public should have a window into the progress FDA is making and the timeline for its implementation. Some examples of timelines and plans related FDA-related work that the public have a right to know include: the work plan and timeline for implementing guidance for improved Patient Medication Information (PMI), reducing the strength-per-pill limit on over-the-counter acetaminophen, releasing the recently updated guidance on clinical trials for analgesic drugs, and final implementation of reclassifications of medical devices.

III. What reforms would help reduce the unnecessary fragmentation of health care data? What reforms would improve the accessibility and usability of health care data for consumers, payers, and providers?

Data resources must be curated. There should be an organized system to periodically review data sources with an eye towards examining: (1) Is the information that is supposed to be available actually available? (2) Is the information truly accessible? (3) Are there opportunities to consolidate or centralize the data to make it more accessible to consumers/advocates? The goal of the review would be to enhance, improve, and increase data available in a more organized way, removing unnecessary overlap.

For example: data on hospital acquired conditions once was on Hospital Compare[8], a site that consumers visited to get comparative information on hospitals. This data was removed and put on data.gov, which required digging to find the same information. Now, that data is being removed from data.gov. Keeping the data available, (or at least linked), on a site that is most often promoted for health information will help consumers find it. Data that reveals how a federal program is working should be public.

Interoperability of electronic health records must be fast-tracked. CMS established the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs[9] with the express purpose of increasing the meaningful use of EHRs to improve the experience

[7] Memo from EMA on publication and access to clinical-trial data is available here.
[8] Available here.
[9] Also known as the "Meaningful Use Program," more information is available here.

and outcomes of health care via improved care coordination and patient engagement. Although there have been some improvements in the initial stages, limited interoperability between providers using different EHR systems is a widely acknowledged problem. The Office of the National Coordinator (ONC) recently solicited comments on a proposal to delay stages 2 and 3 of the program. If they do so—and it is likely they will—they must focus on improving interoperability in the third, and final, stage of the program.

IV. What barriers stand in the way of stakeholders using existing data sources more effectively and what reforms should be made to overcome these barriers?

Data quality must be addressed. Data quality here refers to the completeness and accuracy of the data, a critical issue for improving transparency. Examples include:

- The quality of health data is largely untested, thus unknown. When the federal data (including self-reported data and billing data) are used to rate performance, health care providers often quickly discount the results due to questionable data quality. This discrediting of the data source can cause the public to discount the results and in turn not use the measure results in informing their selection of a health care provider.
- There is a general acceptance of inaccuracies in coded claims data by hospitals and policymakers alike. This must change, as these claims are the only source of electronic information about the care patients received. It should be a priority to ensure the accuracy of data reported to the federal government by providers and used to report provider performance in a comparative way to the public. These data are also used in pay for performance measures designed to improve patient safety and deliver high quality care.
- The federal government conducts a number of audits of claims data. However, the audits are narrowly focused on appropriate billing and fraud. These existing auditing processes should be further developed. The scope of the audit can be expanded to examine data elements and codes most frequently drawn on in performance measurement. Accountability for accuracy of billing data should be enforced.
- Data collected by the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) should be audited for accuracy. Several states validate their hospital-acquired infection data but this is not done nationally. A relatively small federal investment sent to each state to validate this data would lead to more reliable infection reporting.

Data availability must be expanded past Medicare Fee-for-Service. Although we applaud CMS for its substantial progress on making data publicly available, in almost all instances the data is limited to Medicare fee-for-service (FFS) only beneficiaries. The health care provider or facility performance based on only Medicare FFS patients is not necessarily a reflection of the overall performance.

Rather, we need a federal body charged with the collection and reporting of health care provider performance based on broad standardized set of health care data. A commission organized by the Clinton administration considered such an organization. That commission drew comparisons of this body to the Securities and Exchange Commission (SEC), which regulates what data is uniformly made publicly available on businesses so as to ascertain their financial health. The SEC was warranted on the grounds that such information was seen as a necessary public good. Undoubtedly, the sharing of data to assess the performance of health care providers should be a right for all in purchasing health care. Study upon study has documented extreme variation in health care performance in important areas as death and other adverse outcomes. Just as people deserve to know the financial standing of companies they may do business with, people also have a right to learn of the performance of health providers they trust with their life.

Data needs to be timelier. By the time a given health care data set becomes available and measures are computed, the relevance of it reflecting performance today is questionable. For example, for a number of the measures currently on CMS's Hospital Compare website, the time period of the data is July 2009 to June 2012. It is hard to convince the average person that when making a decision about where to have a procedure next month they should seriously consider hospitals' results using data extending back as long as four years. We suggest timeliness requirements for submission and sanctions for unmet timeframes, which would solve current data collection issues and speed the adoption of electronic systems to extract and submit data.

The cost of data should not be borne by private organizations. In most circumstances, there is not a strong business case in measuring performance of health providers and sharing it publicly. Along with this, the cost of data continues to rise and the deployment of state of the art measures (e.g. episode groupers) is increasingly becoming cost-prohibitive. As a result, stewards of public reports defer to using Medicare only data and using homegrown tools. In turn, the data is less reflective of the whole and the results are not as credible as they could be. Furthermore, the requirements for publishing Medicare physician-level data for qualified entities make it cost-prohibitive for nonprofit organizations like Consumer Reports that serve the public.

The measure development enterprise undertaken on the federal level should be a broader effort. CMS already undertakes the development of measurement tools, but typically for the narrow purpose of measuring performance of providers' Medicare FFS business. If CMS can only take on the effort as it relates to Medicare and Medicaid, perhaps the data collection and measurement enterprise should be placed at another HHS agency, such as the CDC or AHRQ. Both agencies already develop and maintain quality measures of provider performance based on all ages or adults (vs. Medicare only).

Ensuring the data is freely available and providing basic tools that turn the data into results of provider performance should be in the purview of the federal government. The federal government should recognize that harnessing the data and dissemination of tools to interpret the results is akin to the SEC that exposes the financial state of businesses operating in the US. In this health care equivalent, an SEC-like body would

ensure uniform quality and cost information and data that are available to evaluate providers.

Consumers' privacy concerns must be addressed. To earn and maintain consumer trust—and permission to use their information—data must be anonymized to protect consumers; it should be impossible to piece together "de-identified" information to form a complete picture of a consumer. Major initiatives like the National Patient-Centered Clinical Research Network (PCORnet) should continue to seek guidance from consumers and consumer advocates to design policies that maximize the data available for important research studies that may improve individual and population health while also honoring consumers' valid concerns about protecting their privacy and ensuring data security.

Data privacy should be granted judiciously. Health care providers should not be given the same privacy protections as their patients. Rather, provider data must be easily identifiable by facility or individual provider so it can be used for quality measurement. This level of transparency is necessary for consumers to make informed decisions in seeking care and for providers to pursue continuous improvement.

For example: The National Practitioner Data Bank (NPDB) is the only database in the country that gathers information about physicians who have identified problems, including discipline by state medical boards, Medicare fraud, malpractice settlements, and actions by hospitals and health plans. Currently, access to this information, which shows a physician's record across all states as well as federal issues, is restricted to specific groups, such as medical boards, hospitals, and health plans. But the identities of these physicians are hidden from public view even though almost all of the information is already public information in other places. As a result, the public can see that an unidentified physician has many problems across numerous states, but cannot actually tell if it is the doctor they are seeing or want to see. Given the mobility of physicians, with many practicing in multiple states and via telemedicine, it is time to open up the NPDB to the public. This would take Congressional action.

Application of the "trade secret" exemption must be limited. The trade secret exemption is used far beyond the purpose for which it was intended, harming consumers. For example:

- Health insurers in 2014 used the trade secret exemption both on the federal level and in some states to limit rate filing information available to the public and circumvent consumers' important role in the rate review process.[10]
- Drug and device manufacturers are exempted from reporting indirect continuing medical education (CME) payments to doctors. CMS recently issued a statement of intent—in the Physician Fee Schedule for 2015—to eliminate this exclusion for CME in the Open Payments program, known as the Sunshine Act, which

[10] See Tampa Bay Times, *Most Florida health insurers conceal 2015 premium prices*, 9 July 2014 available here.

[10]Consumers Union joined with over-70 co-signors to demand that HHS release rate request filings for which insurers claimed trade secret exemption, letter available here.

requires drug and device companies to disclose payments to physicians.[11] We support CMS' movement in this area and hope to see it finalized and carried on to other areas where the exemption is still applied.

Dataflow must include consumers and consumer advocates. Consumers and consumer advocates should be invited to partner in designing measures that matter to them and in testing measures and presentation/access to data. Groups like Consumers Union can provide feedback on whether the data provided is helpful and/or provided in a helpful format.

The breadth of information available must be expanded. In addition to making ongoing data publicly available, consumers and researchers need historical data to measure progress. For example, Hospital Compare has published many measures over the past decade, but the site does not make historical data available. Using web tools, it would be simple for each hospital to have a historical graphic showing improvement over time.

Confusing/misleading billing practices by providers alters the meaning of data. The practice of billing for multiple health care practitioners under a single doctor's identification number is common but confusing and muddies the water for price and quality transparency. This has come to prominent light with the recently released physician billing data, but is an ongoing problem with hospital quality and safety reports. Hospitals are also allowed to report multiple facilities under one provider number. For example, CMS is allowing hospital acquired infections to be reported by hospital systems aggregately rather than reporting performance of each hospital within the system. Many states do not allow such aggregate reporting for infections; disaggregated data reveals that there can be real differences among hospitals within a single "system." If CMS does not have the ability to require each health care provider to use its own identification number, Congress should act to require separate billing identification numbers for each provider, since this data is used for measuring performance.

Thank you again for the opportunity to comment on this extremely important policy area. We hope that you find our suggestions useful, and look forward to working with you on building a health data system that truly serves the public.

Sincerely,

DeAnn Friedholm
Director, Health Reform
Consumers Union

[11] For more information, see Modern Healthcare article and their follow-up article announcing CMS's intent.